APR 17 2002 K020947

Exhibit D

Endoscopy Division

Smith & Nephew, Inc.
160 Dascomb Road, Andover, MA 01810 U.S.A.
Telephone: 978-749-1000
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Smith+Nephew

510(k) Summary
Dyonics InteliJET Reusable Cannulas
Date Prepared: March 21, 2002

This 510(k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810
USA

B. Company Contact

Deborah Connors
Regulatory Affairs Manager

C. Device Name

Trade Name: Dyonics InteliJET™ Reusable Cannulas
Common Name: cannula for arthroscopy pump
Classification Name: Infusion Pump

D. Predicate Devices

The predicate device for this submission are the currently cleared Dyonics InteliJET Reusable Cannulas.

E. Description of Device

The Dyonics InteliJET Reusable Cannulas are used to establish portals to the surgical site during arthroscopic surgical procedures. The Dyonics InteliJET Reusable Cannulas are designed to work in conjunction with the InteliJET Fluid Management System to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

F. Intended Use

The Dyonics InteliJET Reusable Cannulas are indicated for use with the InteliJET Fluid Management System during arthroscopic surgical procedures of the knee, shoulder and small joints to regulate flow of irrigation fluids through the joint to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

G. Comparison of Technological Characteristics

The basic technologies, design and function of the Dyonics InteliJET Reusable Cannulas is not changed by the material modification described in this Premarket Notification Submission. The new material has been demonstrated to meet the requirements for biocompatibility established in ISO 10993-1: 1997. This change raises no new issues of safety and effectiveness.

Deborah Connors
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Smith & Nephew, Inc.
Endoscopy Division
Ms. Deborah Connors
Regulatory Affairs Manager
160 Dascomb Road
Andover, Massachusetts 01810

Re: K020947
Trade Name: Dyonics InteliJET™ Reusable Cannulas
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: March 22, 2002
Received: March 25, 2002

Dear Ms. Connors:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost
for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K020947

Device Name: Dyonics InteliJET Reusable Cannulas

Indications for Use: The Dyonics InteliJET Reusable Cannulas are indicated for use with the InteliJET Fluid Management System during arthroscopic surgical procedures of the knee, shoulder and small joints to regulate flow of irrigation fluids through the joint to maintain intra-articular pressure for uniform distention and clear visualization of the surgical site.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020947

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)